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09/920,607	07/31/2001	Jeremy Minshull	02-106410US	3959
30560	7590	07/13/2007	EXAMINER	
MAXYGEN, INC. INTELLECTUAL PROPERTY DEPARTMENT 515 GALVESTON DRIVE REDWOOD CITY, CA 94063			WESSENDORF, TERESA D	
			ART UNIT	PAPER NUMBER
			1639	
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			07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/920,607

Applicant(s)

MINSHULL ET AL.

Examiner

T. D. Wessendorf

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1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on 25 April 2007.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-135, 137 and 140-160 is/are pending in the application.
- 4a) Of the above claim(s) 1-68, 73-130, 132, 133 and 137 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 69-72, 131, 134-135 and 140-160 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a)  All    b)  Some \*    c)  None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- Notice of References Cited (PTO-892)
- Notice of Draftsperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- Notice of Informal Patent Application
- Other: \_\_\_\_\_

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**DETAILED ACTION**

**Status of Claims**

Claims 1-135, 137 and 140-160 are pending in the application.

Claims 1-68, 73-130, 132-133 and 137 are withdrawn from further consideration as being drawn to non-elected inventions.

Claims 69-72, 131, 134-135 and 140-160 are under examination.

**Specification**

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. For example, pages 74, 83, and 99 have embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

**Response to Arguments**

In amending paragraph at page 99, lines 17-22 (see Applicants' amendment on 4/25/2007) the amendment resulted in an incomplete sentence with the cancellation of the hyperlink.

***Withdrawn Rejections***

In view of applicants' amendments to the claims and arguments, the rejections of the claims under 35 USC 112, second paragraph and 35 USC 102 over Barrett have been withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 69-72, 131, 134-135 and 140-160, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 69 and 145, component (d) is unclear and lacks antecedent basis from © which does not recite that a reaction product detected by detection system corresponds to a data for a storage system.

***Claim Rejections - 35 USC § 103***

Claims 69-72, 131,134, and 140 are rejected under 35 U.S.C. 103(a) as being obvious over Barrett et al. (US Patent 5,482,867) for reasons of record and reiterated below.

Barrett et al. disclose a device and methods of making the device (see e.g. Abstract; col. 2, lines 36-39). The device comprises a solid support (refers to instant claimed solid support) and a plurality of anti-ligands immobilized on predefined regions on the surface of the solid support (refers to instant claimed plurality of enzymes, and claims 71 and 134) wherein the plurality of regions on the surface of the solid support contain the same or different anti-ligands (see e.g. col. 2, lines 36-39; col. 5, lines 4-20; col. 6, lines 52-59). The surface of the solid support is composed of material such as polymer, e.g. aryl acetylenes, on which the plurality of anti-ligands is immobilized (refers to instant claimed non-biological polymeric matrix, and claims 71 and 140) (see e.g. col. 4, lines 3-7; col. 7, line 66 thru col. 8, line 21). The anti-ligands include naturally occurring or manmade molecules such as enzymes (refers to instant claimed artificial enzyme variant and claim 131) (see e.g. col. 4, lines 34-60; col. 19, line 60 thru col. 20, line 20). The device also comprises a detection system such as a scanning fluorescence microscope that include and IBM

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compatible PC for use in screening methods (refers to instant claimed detection system and data storage system, and instant claim 72) and further comprises fluorescent maker for use in screening methods (refers to instant claimed 'optically detectable element' of claim 70) (see e.g. col. 21, lines 7-54; col. 29, lines 19-29; col. 31, line 15 thru col. 32, line 12; fig. 10). Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of the properties of the instant claimed 'enzyme/artificial enzyme variant' (i.e. 'having different small molecule substrate specificities', 'exhibits enhanced stability relative to the natural enzyme', and 'has specificity for a metabolite'). The claimed invention appears to be an obvious variation of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference 'enzyme/artificial enzyme variant'. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed 'enzyme/artificial enzyme variant' is different from the one taught by prior art and to establish the patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Exparte Gray* 10 USPQ2d 1922 (PTO Bd. Pat. App. & Int.

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1989). Furthermore, functionalities of the instant claimed 'detection system' and 'data storage system' are not giving any patentable weight since these functionalities does not impart any structural limitation to the instant claimed apparatus, i.e. the 'detection system' and 'data storage system'. See MPEP § 2115, which states: MATERIAL OR ARTICLE WORKED UPON DOES NOT LIMIT APPARATUS CLAIMS "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." Ex parte Thibault, 16 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In re Young, 75 F.2d \*996, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Claims 145-150 and 152 are rejected under 35 U.S.C. 103(a) as being obvious over Barrett et al. (US Patent 5,482,867) for reasons as repeated below.

The instant invention recites a device, i.e. a biosensor for detecting different small molecules in a sample. The structural features of the device comprise (a) a solid support; (b) a plurality of enzymes immobilized on the solid support; (c) a detection system; and (d) a data storage system. The plurality

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of enzymes comprises an artificial enzyme variant of a naturally occurring enzyme. The enzymes comprise different small molecule substrate specificities and a non-naturally occurring catalytic specificity. These limitations are interpreted as the functionality/property of the instant claimed enzyme/artificial enzyme variant. The detection system is capable of detecting a reaction product from a reaction catalyzed by each of the enzymes in the plurality of enzymes, either directly or indirectly. This is interpreted as a functionality of the instant claimed detection system. The limitation of "in which data corresponding to detected reaction product from reactions catalyzed by each of the enzymes in the plurality of enzymes is recorded" is interpreted as a functionality of the instant claimed data storage system. Barrett et al. disclose a device and methods of making the device (see e.g. Abstract; col. 2, lines 36-39). The device comprises a solid support (refers to instant claimed solid support) and a plurality of anti-ligands immobilized on predefined regions on the surface of the solid support (refers to instant claimed plurality of enzymes, and claims 147 and 150) wherein the plurality of regions on the surface of the solid support contain the same or different anti-ligands (see e.g. col. 2, lines 36-39; col. 5, lines 4-20; col. 6, lines 52-59). The surface of the solid support is composed of



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material such as polymer, e.g. aryl acetylenes, on which the plurality of anti-ligands is immobilized (refers to instant claimed non-biological polymeric matrix, and claims 147 and 152) (see e.g. col. 4, lines 3-7; col. 7, line 66 thru col. 8, line 21). The anti-ligands include naturally occurring or manmade molecules such as enzymes (refers to instant claimed artificial enzyme variant and claim 149) (see e.g. col. 4, lines 34-60; col. 19, line 60 thru col. 20, line 20). The device also comprises a detection system such as a scanning fluorescence microscope that include and IBM compatible PC for use in screening methods (refers to instant claimed detection system and data storage system, and instant claims 148 and 149) and further comprises fluorescent maker for use in screening methods (refers to instant claimed 'optically detectable element' of claim 146) (see e.g. col. 21, lines 7-54; col. 29, lines 19-29; col. 31, line 15 thru col. 32, line 12; fig. 10). Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of the properties of the instant claimed 'enzyme/artificial enzyme variant' (i.e. 'having different small molecule substrate specificities', and 'a non-naturally occurring catalytic specificity', and 'has specificity for a metabolite'). The claimed invention appears to be the same or obvious variations of the reference teachings, absent a

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showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference 'enzyme/ artificial enzyme variant'. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed 'enzyme/artificial enzyme variant' is different from the one taught by prior art and to establish the patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922 (PTO Bd. Pat. App. & Int. 1989). Furthermore, functionalities of the instant claimed 'detection system' and 'data storage system' are not giving any patentable weight since these functionalities does not impart any structural limitation to the instant claimed apparatus, i.e. the 'detection system' and 'data storage system'. See MPEP § 2115, which states: MATERIAL OR ARTICLE WORKED UPON DOES NOT LIMIT APPARATUS CLAIMS "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In

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re Young, 75 F.2d \*996, 25 USPQ 69 (CCPA 1935) (as restated  
inln re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

***Claim Rejections - 35 USC 102/\$ 103***

Claims 69-72, 131,134, 135, 140-144, 157, and 158 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Keen (US Patent 6,060,327; effective filing date of 5/14/1997). The instant invention recites a device, i.e. a biosensor for detecting different small molecules in a sample. The structural features of the device comprise (a) a solid support; (b) a plurality of enzymes immobilized on the solid support; (c) a detection system; and (d) a data storage system. The plurality of enzymes comprises an artificial enzyme variant of a naturally occurring enzyme. The enzymes comprise different small molecule substrate specificities and exhibits enhanced stability relative to the natural enzyme. These limitations are interpreted as the functionality/property of the instant claimed enzyme/artificial enzyme variant. The detection system is capable of detecting a reaction product from a reaction catalyzed by each of the enzymes in the plurality of enzymes, either directly or indirectly. This is interpreted as a functionality of the instant claimed detection system. The limitation of "in which

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data corresponding to detected reaction product from reactions catalyzed by each of the enzymes in the plurality of enzymes is recorded" is interpreted as a functionality of the instant claimed data storage system. Keen discloses a sensor device (see e.g. Abstract; col. 7, line 44 thru col. 8, line 28; col. 9, lines 3-24; col. 11, lines 45-60). The device comprises a plurality of conductive polymer strands (refers to instant claimed non-biological polymeric matrix of claim 71), a plurality of recognition head groups having an affinity for the analyte component and attached to the first ends of the conductive polymer strands (refers to instant claimed "a plurality of enzymes immobilized on the solid support", and claims 71, 131, 134 and 140), and an electrode substrate attached to the conductive polymer strands at the second ends (refers to instant claimed solid support, and claims 70 and 142) (see e.g. col. 7, line 44 thru col. 8, line 28; col. 9, lines 3-24; col. 12, line 38 thru col. 13, line 53; figs. 2 and 3). The device is also divided into a plurality of regions wherein each comprises a different head groups that detect different analytes such that each of these regions will be separately addressable by electronic circuitry to uniquely identify the presence of the particular analyte component (refers to instant claims 134 and 135) (see e.g. col. 10, lines 13-28; col. 14, line 57 thru col.

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15, line 22). The types of polymer strands include polymers such as ferrocene polymers (refers to instant claimed non-biological polymeric matrix, and claim 140) (see e.g. col. 25, lines 3-65), and wherein the ferrocene of the ferrocene polymers is a mediator as evidence by Hale et al. (see e.g. pg. 3483, fig. 2) (refers to instant claims 143, 144, 157, and 158). The types of head groups include enzymes such as lipases and oxidoreductases and enzymes can be obtained from combinatorial libraries (refers to instant artificial enzyme variant and claim 131) (see e.g. col. 26, lines 5-36; col. 31, lines 16-40). The device is connected to a digital multimeter that measures the circuit output (refers to instant claimed detection system, and claims 70 and 141) (see e.g. col. 39, lines 7-45; figs 5 and 6) or connected to instruments such as a pen-based digital meter or lab-based instruments (refers to instant claimed detection system/data storage system, and claim 72) (see e.g. col. 37, line 66 thru col. 38, line 63; col. 39, line 46 thru col. 40, line 3). Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of the properties of the instant claimed 'enzyme/artificial enzyme variant' (i.e. 'having different small molecule substrate specificities', 'exhibits enhanced stability relative to the natural enzyme', and 'has specificity for a metabolite'). The

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claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference 'enzyme/artificial enzyme variant'. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed 'enzyme/artificial enzyme variant' is different from the one taught by prior art and to establish the patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922 (PTO Bd. Pat. App. & Int. 1989). Furthermore, functionalities of the instant claimed 'detection system' and 'data storage system' are not giving any patentable weight since these functionalities does not impart any structural limitation to the instant claimed apparatus, i.e. the 'detection system' and 'data storage system'. See MPEP § 2115, which states: MATERIAL OR ARTICLE WORKED UPON DOES NOT LIMIT APPARATUS CLAIMS "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart

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patentability to the claims." In re Young, 75 F.2d \*996, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). Therefore, the device of Keen anticipates the presently claimed device

Claims 145-156, 159, and 160 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Keen (US Patent 6,060,327; effective filing date of 5/14/1997). The instant invention recites a device, i.e. a biosensor for detecting different small molecules in a sample. The structural features of the device comprise (a) a solid support; (b) a plurality of enzymes immobilized on the solid support; (c) a detection system; and (d) a data storage system. The plurality of enzymes comprises an artificial enzyme variant of a naturally occurring enzyme. The enzymes comprise different small molecule substrate specificities and a non-naturally occurring catalytic specificity. These limitations are interpreted as the functionality~property of the instant claimed enzyme/artificial enzyme variant. The detection system is capable of detecting a reaction product from a reaction catalyzed by each of the enzymes in the plurality of enzymes, either directly or indirectly. This is interpreted as a functionality of the instant claimed detection system. The limitation of "in which data corresponding to detected reaction

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product from reactions catalyzed by each of the enzymes in the plurality of enzymes is recorded'" is interpreted as a functionality of the instant claimed data storage system. Keen discloses a sensor device (see e.g. Abstract; col. 7, line 44 thru col. 8, line 28; col. 9, lines 3-24; col. 11, lines 45-60). The device comprises a plurality of conductive polymer strands (refers to instant claimed non-biological polymeric matrix of claim 177), a plurality of recognition head groups having an affinity for the analyte component and attached to the first ends of the conductive polymer strands (refers to instant claimed "a plurality of enzymes immobilized on the solid support", and claims 147, 149, 150 and 152), and an electrode substrate attached to the conductive polymer strands at the second ends (refers to instant claimed solid support, and claims 146 and 154) (see e.g. col. 7, line 44 thru col. 8, line 28; col. 9, lines 3-24; col. 12, line 38 thru col. 13, line 53; figs. 2 and 3). The device is also divided into a plurality of regions wherein each comprises a different headgroups that detect different analytes such that each of these regions will be separately addressable by electronic circuitry to uniquely identify the presence of the particular analyte component (refers to instant claims 150 and 151) (see e.g. col. 10, lines 13-28; col. 14, line 57 thru col. 15, line 22). The types of



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polymer strands include polymers such as ferrocene polymers (refers to instant claimed non-biological polymeric matrix, and claim 151) (see e.g. col. 25, lines 3-65), and wherein the ferrocene of the ferrocene polymers is a mediator as evidenced by Hale et al. (see e.g. pg. 3483, fig. 2) (refers to instant claims 155, 156, 159, and 160). The types of headgroups include enzymes such as lipases and oxidoreductases and enzymes can be obtained from combinatorial libraries (refers to instant artificial enzyme variant and claim 149) (see e.g. col. 26, lines 5-36; col. 31, lines 16-40). The device is connected to a digital multimeter that measures the circuit output (refers to instant claimed detection system, and claims 146 and 153) (see e.g. col. 39, lines 7-45; figs 5 and 6) or connected to instruments such as a pen-based digital meter or lab-based instruments (refers to instant claimed detection system/data storage system, and claim 148) (see e.g. col. 37, line 66 thru col. 38, line 63; col. 39, line 46 thru col. 40, line 3). Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of the properties of the instant claimed 'enzyme/artificial enzyme variant' (i.e. 'having different small molecule substrate specificities', and 'a non-naturally occurring catalytic specificity', and 'has specificity for a metabolite'). The claimed invention appears to be the same or

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obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference 'enzyme/ artificial enzyme variant'. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed 'enzyme/artificial enzyme variant' is different from the one taught by prior art and to establish the patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Exparte Gray* 10 USPQ2d 1922 (PTO Bd. Pat. App. & Int. 1989). Furthermore, functionalities of the instant claimed 'detection system' and 'data storage system' are not giving any patentable weight since these functionalities does not impart any structural limitation to the instant claimed apparatus, i.e. the 'detection system' and 'data storage system'. See MPEP § 2115, which states: MATERIAL OR ARTICLE WORKED UPON DOES NOT LIMIT APPARATUS CLAIMS "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In

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re Young, 75 F.2d \*996, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Therefore, the device of Keen anticipates the presently claimed device.

### ***Response to Arguments***

Applicants recognize that the Keen patent describes a sensor for sensing the presence of an analyte component that has a plurality of molecular recognition headgroups having affinity for the analyte component attached to a conductive polymer. But argue that neither Barrett et al. nor Keen describe, inter alia, a biosensor comprising a plurality of enzymes "wherein the plurality of enzymes comprises an artificial enzyme variant of a naturally occurring enzyme, wherein the artificial enzyme variant exhibits enhanced stability relative to the naturally occurring enzyme." With regards to independent claim 145, Barrett et al. and Keen both fail to describe, inter alia, a biosensor comprising a plurality of enzymes "wherein the plurality of enzymes comprises an artificial enzyme variant of a naturally occurring enzyme, wherein the artificial enzyme variant comprises a non-naturally occurring catalytic specificity." Applicants state that Barrett provide a laundry list of compounds, including a generic reference to "enzymes".

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In response, it would be within the ordinary skill in the art to pick and choose from the list, which are known prior art biosensors, the known interacting components e.g., enzyme-substrate (analyte, as claimed) to enable detection of one of the substance.

As held by the majority in *Merck & Co. Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 10 USPQ 2d 1843 (Fed. Cir. 1989), at 10 USPQ 2d 1846:

That the '813 patent discloses a multitude of effective combinations does not render any particular formulation less obvious. This is especially true because the claimed composition is used for the identical purpose taught by the prior art. See *In re Corkill*, 771 F.2d 1496, 1500, 226 USPQ 1005, 1008 (Fed. Cir. 1985) (obviousness rejection of claims affirmed in light of prior art teaching that "hydrated zeolites will work" in detergent formulations, even though "the inventors selected the zeolites of the claims from among "thousands of compounds"); *In re Susi*, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971) (obviousness rejection affirmed where the disclosure of the prior art was "huge, but it undeniably include[d] at least some of the compounds recited in appellants generic claims and it is of a class of chemicals to be used for the same purpose as appellant's additives").

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Applicants state that the Barrett et al. patent's generic reference to "enzymes" is far too deficient in detail for one to make any conclusion as to what features of "enzymes" are being taught.

In reply, it is well known in the art that given an enzyme one can readily determine the features the enzyme exhibits. Note that the claimed variants of enzymes is far more generic than Barrett's disclosure of an enzyme. It is well known in the art that a plurality of enzymes (i.e., variants of enzymes) which are useful for screening are screened for enzymes that have a better (enhanced, as claimed) properties whether stability, specificity and other known properties/features of enzymes than that of the parent enzyme.

Applicants state that in the Keen patent, the disclosure of a class of enzymes only provides information on the type of activity of the enzyme. The Keen patent is void of any details as to other properties of the enzymes. Similarly, disclosure that the enzymes can be from combinatorial and commercial libraries has no bearing on the properties of the enzymes. The features of enhanced stability and a non-natural specificity do not necessarily flow from the teaching of Keen.

In reply, the teachings of a combinatorial library of Keen, which are known in the art to comprise variants of the parent

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e.g., enzyme when screened are known to result to a better property i.e., enhanced property than the parent enzyme. Enzyme is known for its catalytic activity. Hence, it would be within the skill in the art to determine whether the specific enzymes recited by Keen e.g., lipase or glucose oxidase would have the enhanced property after library screening or catalytic activity upon reaction with its specific substrate. Accordingly, Keen anticipates the claimed biosensors as all the components of the biosensors are recited. The claimed property of the known enzyme would be within the skill in the art to determine given the known techniques in the art as taught by Keen.

No claim is allowed.

#### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

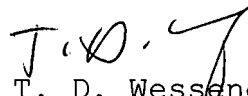
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This application contains claims 1-68, 73-130, 132-133 and 137 drawn to non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw  
June 26, 2007